

**International Conference on Harmonization (ICH)**  
**M2 EWG Meeting - Summary**  
**Tokyo, 28 February to 02 March 2000**

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**Participants:**

**EU:** Esteban Gonzalez Juarros, Karel de Neef, Stan van Belkum  
**EFPIA:** Gabriele Disselhoff, Andrew Marr  
**PhRMA:** Kris Arora, Bob Hizer, Rick Bowen,  
**FDA:** Greg Brolund (Rapporteur), Leo McNamara  
**JPMA:** Yuichi Nagoshi, Tetsuro Shimokariya, Hitoshi Asano, Harv Martens, Keiji Sawamukai  
**MHW:** Mihoko Okada, Mitsuo Saito, Fumiko Imamura  
**Observer:** Bob Kapitany

The tasks accomplished and the decisions agreed are the following:

**eCTD**

- The EWG discussed the lessons learned from the “proofs of concept”, which were agreed during the last EWG meeting in Washington. The original scope has changed and led to the concept for the eCTD backbone.
- Three subgroups were formed to cope with the tasks to be fulfilled
  - the specification group developed a draft outline for the eCTD specification document
  - the backbone group started the design of the eCTD backbone, which should
    - support technology changes over time
    - support creation, transmission and review of the dossier
  - the CTD analysis group started the analysis of the CTD draft Step 2 document to identify the functionality needed in each section of the eCTD
    - they requested feedback from the CTD groups on capabilities needed in the eCTD
    - contact persons from the CTD Q, E and S groups were decided
- Regulatory authorities discussed the submission life cycle in their respective regions in order to make sure there is a clear understanding by all parties of the way submissions are received, reviewed and updated over the life of a submission.
- The EWG demonstrated an example of eCTD reviewer functionality to the ICH SC, CTD E and CTD Q EWGs
- A timetable was agreed for the work products of the three subgroups
  - a 1<sup>st</sup> draft should be available within the respective subgroup and circulated to the M2 EWG by mid May
  - comments should be received by mid June
  - consolidated comments & revised drafts by end of June to be reviewed at the July EWG meeting

**E2BM**

- The EWG heard two proposals resulting from the E2BM group meeting. The first recommendation related to lengthening of field B.4.k.19 from 100 to 200 (as in the ICSR version 2 specification). This proposal was unanimously agreed.  
The second recommendation related to specifying the time stamp to be used for field M.1.7. The M2 EWG reverted the issue back to the E2BM group for further consideration.

**General**

- The EWG presented status and results to the ICH SC
- The next full M2 meeting will take place in Brussels, from July 17 - 20, 2000, as proposed for the ICH Steering Committee meeting.